



American Society of Pediatric Nephrology

6728 Old McLean Village Drive, McLean, VA 22101, ph. 703.556.9222; fax 703.556.8729

August 31, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model (CMS-1749-P)

Dear Ms. Brooks-LaSure:

The American Society of Pediatric Nephrology (ASPN) is pleased to provide these comments on the CY 2022 End-Stage Renal Disease (ESRD) Prospective System and Quality Incentive Program proposed rule, including responses to two Center for Medicare & Medicaid Services (CMS) requests for information that specifically address payment for pediatric ESRD care and pediatric cost report information. Founded in 1969, ASPN is a professional society composed of pediatric nephrologists whose goal is to promote optimal care for children with kidney disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. ASPN currently has over 700 members, making it the primary representative of the Pediatric Nephrology community in North America.

We will be providing comments on the following provisions of this rule:

- Updates to the CY 2022 Outlier Policy
- Request for Information for Pediatric Dialysis Payment
- Request for information on the Pediatric Dialysis Cost Report
- ESRD Treatment Choices Model
- Quality Incentive Program Extraordinary Circumstances, Flexibility, and Suppression Policy
- Kt/V Comprehensive Clinical Measure
- ESRD Facility Equity Score
- Addressing Health Equity through Data Stratification
- Patient COVID-19 Vaccination Measure

Updates to the CY 2022 Outlier Policy

ASPN is concerned about the significant decreases to both the fixed-dollar loss and Medicare allowed payment amounts as the cost of delivering pediatric ESRD care is not appropriately reimbursed by the existing bundle or either of these outlier adjustments. We do recognize that CMS is constrained by the existing outlier methodology, however, and we look forward to working with the agency to implement a reimbursement policy that accurately reflects the complexities and costs of pediatric ESRD care. We

have provided extensive comments in response to the two requests for information (RFI) on pediatric topics.

Request for Information for Pediatric Dialysis Payment

ASPN thanks CMS for including this RFI on pediatric dialysis payment and is providing responses to the following questions:

- Does the magnitude of total costs and pediatric multipliers reflect ESRD facilities' actual incurred costs? If not, what specific costs are not being reported on claims and/or cost reports?

No, the total costs of ESRD care delivered to pediatric dialysis patients are not covered by the current ESRD bundled payment and existing pediatric multipliers. ASPN collected data from a number of pediatric dialysis units located at children's hospitals and the self-reported average costs per in-center dialysis treatment ranged from \$585.40 to \$1587.32. The Society also received a comparison of pediatric and adult ESRD-related costs from a pediatric dialysis unit run by a large dialysis organization (LDO). Such a facility is positioned to spend the least on pediatric supplies and staff, given that it can benefit from the LDO's economy of volume. That data showed that pediatric in-center hemodialysis cost twice as much as adult dialysis care delivered at units affiliated with that LDO.

Historically, there has been recognition that dialysis payments based on the costs incurred to provide adult care is insufficient to cover the costs of pediatric dialysis. CMS allowed pediatric dialysis facilities to apply for exceptions to obtain higher rates based on actual facility costs for more than two decades, and then from 2005-2011 applied a 1.62 multiplier for payments to all patients younger than 18 years under the period of basic case-mix adjustment methodology. With the subsequent institution of the bundled prospective payment system, pediatric adjusters were significantly reduced despite the costs of pediatric dialysis remaining significantly higher than those incurred with adult dialysis.

While adult and pediatric centers employ many of the same categories of providers – nurses, social workers, dietitians, nurse managers, nurse practitioners, and nephrologists – those who treat children must have specialized training in pediatric care. This specialized training reduces the potential pool of qualified individuals and increases personnel costs in pediatric dialysis units, an expense not captured by CMS. Moreover, the staffing models used in pediatric dialysis facilities need to reflect the increased individual effort often needed for the safe provision of dialysis to the pediatric patient or the increased time needed to educate and counsel the responsible adult caring for the child at home, resulting in more staff needed per pediatric dialysis patient (staff to patient ratios often 1:1 or 1:2) than for adult dialysis. Child life specialists and teachers also play integral roles in the care delivered to pediatric dialysis patients and the cost of retaining these resources is not currently captured by claims or cost reports.

Similar higher expenses in a pediatric dialysis unit setting applies to dialysis supplies included in the bundled payment. Although most supplies needed in pediatric ESRD care are also used in adult dialysis, pediatric facilities need to be stocked to care for patients who range in size from infants weighing a few kilograms to fully-grown adolescents of large adult size. Accordingly, there often needs to be a wider array of equipment and supplies stocked, with less reliance on standard supplies applicable to almost any patient. This pediatric difference pertains to basic dialysis supplies such as blood lines and dialyzers, as well as to equipment. Another unique pediatric supply cost is items used to occupy children throughout the dialysis session (e.g., books, crafts) so that they are cooperative and do not cause technical complications with dialysis circuit integrity during a dialysis session.

- If duration of treatment is not a valid proxy for composite rate costs per treatment, what are alternative proxies to consider?

Duration of treatment is not a valid proxy for composite rate costs per treatment for pediatric care. Instead, ASPN recommends that a combination of age, weight, and pediatric-specific comorbidities be used as a proxy for composite rate costs. The Society has compiled the following list of pediatric comorbidities for CMS:

- Failure to thrive/feeding disorders – 80% of children under 6 years of age require a G-tube and feeding pump for management of oral aversion or supplemental enteral nutrition to promote growth and ensure appropriate cognitive development
- Congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal)
- Congenital bladder/urinary tract anomalies
- Non-kidney solid organ or stem cell transplant
- Neurocognitive impairment
- Global developmental delay
- Cerebral palsy
- Seizure disorder
- Chronic lung disease (including dependency on CPAP and ventilators)
- Inability to ambulate or transfer

Although all of these comorbidities significantly impact the provision of pediatric dialysis care, neurocognitive impairment and global developmental delay are often more longitudinally complex since they continue to pose significant management challenges even as the child ages, especially when there are no treatments or procedures that can readily ameliorate the underlying condition. Adolescents or young adults with profound neurocognitive impairment or global developmental delay continue to require complex care despite their age and size, and often require a much more intense utilization of staff resources throughout their lives.

In previous correspondence with CMS, ASPN has also suggested that the costs of pediatric care can be broken down into the following age groups: <6 years old, 6-11 years old, and 12-18 years old. Treating the typical dialysis patient who is a young child of small size usually requires more staff resources and specialized equipment than treating the typical older and larger pediatric dialysis patient. Generally, care becomes less resource-intensive as the child becomes older and more cognitively mature and as the child grows and approaches adult body size. Although there are exceptions to this expectation, especially in the setting of patients with global developmental delay, the majority of pediatric dialysis facilities find that younger and smaller children require the most resources, with needs becoming less intense by adolescence.

- What, if any, are the specific concerns about incorporating pediatric patients into the estimation of multipliers for both the adult and pediatric populations?

According to the most recent United States Renal Data System (USRDS) report, there are 5,405 pediatric patients with prevalent ESRD; of that group, 663 are currently treated by hemodialysis.¹ Generally, one third of pediatric dialysis patients are on Medicare, meaning approximately 220 children on hemodialysis have Medicare. Such figures underscore how small the pediatric dialysis Medicare population is, and in fact, the recent report from the December 2020 Technical Expert Panel emphasized this position by pointing out that adults make up 99.86% of the ESRD population on Medicare – meaning

¹ <https://adr.usrds.org/2020/end-stage-renal-disease/7-%20esrd-among-children-and-adolescents>

that children with ESRD make up only a miniscule 0.14% of the total.² Given the extremely small number of pediatric patients contributing to the entire data pool by which multipliers would be calculated, any multiplier derived with combined pediatric and adult data would essentially only reflect the adult population.

- What are the issues facing pediatric billing and accounting staff with regard to completion of claims and cost reports? How can these problems be remedied?

Pediatric dialysis facilities are most commonly affiliated with freestanding children's hospitals where experience and expertise in Medicare reporting and billing tends to be very limited because pediatric dialysis and transplant patients are often the facilities' only Medicare beneficiaries. ASPN has taken steps to educate the billing and accounting staff of pediatric dialysis facilities with limited effect. These institutions have often made an administrative decision that the burden and complexity of reporting so outweigh any revenue generated that few facility resources will be allotted to Medicare reporting. Streamlining the reporting and making it more consistent with reporting required from the state Medicaid programs or the private payers would improve the reporting.

Request for Information on the Pediatric Cost Report

CMS has requested comments on these potential changes to cost reports as well as the questions. ASPN is pleased to provide the following detailed responses that we believe will improve the quality of the data the agency receives:

- What degree of specificity is needed in the reporting of pediatric dialysis costs?

ASPN has suggested the following changes be made to the cost reports to better capture pediatric-specific costs.

Suggested Revisions to CMS Cost Report

Link [here](#) to FORM CMS-265-11

- Include Breakdown of Patient Age Groups (**page 2, line 3**):

3	Number of patients currently in dialysis program	
a)		less than 6 years old
b)		6-11 years old
c)		12-18 years old
d)		19-25 years old (includes transition to adult care)
e)	26 years or older, if neuro-cognitive challenges/other medical challenges, require specialized care at pediatric center	

- Pediatric-specific Supplies (**page 4, line 9**):

9	0900	Supplies*
10		Pediatric-specific supplies

² <https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf>

- Pediatric-specific supplies including pediatric dialyzers and special lines (pediatric, neonatal) as well as CritLine supplies for safe fluid removal
- Pediatric unit with percentage of pediatric patients over 15% would fill out pediatric line. (NOTE: This is to capture pediatric patients in adult units.)
- Facility Employees (**page 2, lines 22-31**): Add a sub-line for pediatric staff under the adult staff line

23	Registered Nurses
24	Registered Nurses with pediatric experience
25	Licensed Practical Nurses
26	Nurses' Aides
27	Technicians
28	Social Workers
29	Dieticians
30	Pediatric dietitians
ASPEN Recommendation	Child life specialists
31	Administrative
32	Management
33	Other (Specify)
34	Designated as a pediatric unit (>50% patients <18 years old)

- Are there dialysis supply costs associated with the treatment of pediatric patients that cannot be reported currently on the cost reports? If so, please specify?

Yes, there are supply costs associated with pediatric care not currently captured by the cost reports. While most supplies utilized in pediatric ESRD care are used in adult dialysis and are represented on cost reports and included in the bundle, there are specific supply costs for pediatric care not captured. For instance, pediatric units are required to have supplies of equipment of various sizes to treat children ranging from infants to young adult, resulting in a wider array of dialysis lines and dialyzers, emergency supplies, cardiorespiratory monitors, blood pressure devices and cuffs, scales and other measurement tools.

ASPEN consulted with a number of pediatric facilities located in children's hospitals and what follows is a more detailed list of the dialyzers and lines they must stock and the estimated costs.

Item	Estimated cost per item
Dialyzers	
0.4M2 Dialyzer	\$27.92
0.6 M2 Dialyzer	\$53.90
1.4 M2 Dialyzer	\$10.07
2.5 M2 Dialyzer	\$16.25
Blood Lines	
Neonatal Line	\$16.06
Pediatric Line	\$9.63
Adult Line	\$3.37
Very Low Volume Blood Segment Line	\$31.92
Low Volume Blood Segment Line	\$12.19
Adult Volume Blood Segment Line	\$3.66

Moderate Volume Blood Segment Line	\$3.09
Crit Line Adapter (needed for each treatment)	\$2.25

- To what extent can providers differentiate dialysis labor costs for adult versus pediatric patients?

The majority of pediatric patients are dialyzed with staff ratios of 1:1 or 1:2, differing from adult units which have staff ratios of 1:4 or 1:6. Additionally, adult units rely heavily on dialysis technicians, whereas technicians are rarer in pediatric facilities due to the complexity of care and pediatric comorbidities requiring specific nursing expertise. Specialized pediatric training is required for all staff.

- What obstacles do providers face in reporting pediatric specific costs of dialysis treatment? How can these obstacles be overcome?

The very small pediatric dialysis patient population receives care in units spread out across the country, complicating the reporting of comprehensive and accurate information. Freestanding children's hospitals do not have other Medicare patients outside of the ESRD population and do not typically allocate resources to gain significant expertise with Medicare reporting, since for any one facility this represents a very small population with very limited revenue generation. These obstacles could be overcome by streamlining the reporting required and making it more consistent with reporting required from the state Medicaid programs or private payers.

- Pediatric dialysis patients comprise a small number of patients in ESRD facilities other than children's hospitals or medical centers. How can pediatric dialysis costs be reported in non-specialized ESRD facilities that predominantly serve adult patients without undue burden on the provider?

In facilities that typically serve adults, there are already greater resources devoted to filing the cost report than in children's hospitals, and the extremely small number of children requiring this data from any single non-pediatric dialysis unit should make the likelihood of undue burden very small. In a unit that almost exclusively dialyzes adults, it should also be easier to break down pertinent costs for outliers such as pediatric supplies. Moreover, since many of these adult facilities do not have pediatric specific services but attempt to fit their pediatric patients into their usual adult care structure, there may be limited pediatric-specific costs to report in the first place.

ESRD Treatment Choices Model

ASPN supports the goals of the ESRD Treatment Choices (ETC) model to increase the rates of kidney transplantation and home dialysis. Emphasis on home dialysis and transplantation is already the hallmark of pediatric ESRD care. The 2019 USRDS annual report demonstrates this emphasis with both higher incident and prevalent rates of home dialysis and transplantation in pediatric ESRD patients than adult patients. In incident children, 28% received home dialysis and 21% received a pre-emptive kidney transplant. In prevalent children undergoing ESRD treatment, 10% receive home treatment and 73% are transplanted.

Despite the alignment of treatment goals in ETC with the pediatric nephrology community's current record of higher desired outcomes for ESRD treatment, ASPN remains concerned that the ETC model may come to include some patients in pediatric centers, despite apparent attempts to exclude pediatric nephrology from the model.

Currently, pediatric patients under 18 years of age are excluded from the ETC model, recognizing that pediatric ESRD patients often have rare medical conditions/co-morbidities with different care needs and costs than typical adult ESRD patients. Patients 18 years or older who may be dialyzed in pediatric facilities would not be excluded, however, although this population is also different from a typical adult dialysis facility population.

Young adults who continue to be treated by pediatric nephrologists in pediatric facilities after they turn 18 years old tend to be a particularly medically complex group of patients who have not met the medical requirements for transition to adult care. They often have significant neurocognitive impairment and global developmental delay that necessitate continued access to care only available in pediatric dialysis centers, such as child life specialists, specialized nursing, or specialized pediatric equipment.

With respect to kidney transplant or home dialysis, these young adults also differ in meaningful ways from typical pediatric patients. Dialysis is a bridge to transplant for the overwhelming majority of pediatric ESRD patients, but many of these young adults may not be transplant candidates given their medical complexity or family preference. Moreover, although ASPN agrees that home dialysis is preferable to in-center dialysis whenever possible, many of these young adults are not candidates for home dialysis given their neurocognitive impairment and global developmental delay. In those who may potentially be home dialysis candidates, many have already been on peritoneal dialysis but returned to in-center treatment because of challenges with peritoneal membrane function and an inability to consider home hemodialysis due to neurocognitive issues with inability to cooperate with home hemodialysis sessions.

In many ways, these young patients who continue to receive care in pediatric dialysis facilities face chronic health challenges more akin to adult patients in skilled nursing facilities than either the typical pediatric or adult ESRD patient. The ETC model excludes adult ESRD patients in hospice, nursing homes, or skilled nursing facilities, those diagnosed with dementia, or those receiving dialysis for acute kidney injury because they differ significantly from the typical dialysis patient. ASPN recognizes that the Innovation Center prefers not to categorically exclude patients from participation in models, but believes that our patients 18 years and older treated in pediatric facilities are substantially similar to those categories of adult patients already excluded from the ETC model. ASPN suggests that all patients in a pediatric facility be excluded from ETC regardless of age.

Quality Incentive Program Extraordinary Circumstances, Flexibility, and Suppression Policy

ASPN supports the blanket extension of CY 2022 clinical reporting deadlines, given data reporting challenges created by the ongoing public health emergency and the ESRD Quality Reporting System. ASPN additionally supports the proposed measure suppression policy, as this policy will avoid penalizing facilities based on data that may be distorted by the COVID-19 pandemic.

Kt/V Comprehensive Clinical Measure

ASPN supports the proposal by the Kidney Care Partners (KCP) to use distinct adult and pediatric hemodialysis and peritoneal dialysis adequacy measures endorsed by the National Quality Forum. As noted by KCP, a pooled approach combining both pediatric and adult patients or both dialysis modalities limits the ability to determine performance on specific populations or specific modalities. Separation of these measures will improve clinical insight into both the pediatric and adult dialysis populations.

Facility Equity Score

Health inequity in pediatric kidney disease is pervasive and persistent. Black children are significantly less likely to receive kidney transplants, wait longer to receive transplants, and are

disproportionately impacted by chronic kidney disease overall.³ Disparities in pediatric kidney care also extend to treatment modalities, with all racial and ethnic minority children being significantly less likely to receive home dialysis treatment than white children.⁴

These disparities grow out of existing policies and regulations that exacerbate health inequities by relying on inaccurate assumptions about the impact of race and ethnicity on kidney care. Race is a social construct with little biological relevance.⁵ In many cases, the use of race and ethnicity in clinical algorithms contributes to practices that delay or reduce access to care for patients who identify as black or African American. For example, our black or African American patients can experience delays in listing for kidney transplant because of the race-based correction of estimations of glomerular filtration rate, a metric that is key in determining eligibility for transplantation.⁶

ASPN supports the concept of an ESRD facility equity score, pending additional detail on its implementation, as this scoring may bring to light ways to address persistent inequalities in outcome for children with kidney disease. To ensure transparency with the scoring process and to help make certain providers are best positioned to address any identified inequities, CMS should work with ASPN and others in the kidney community to identify social risk factors that would be used to develop an equity score. In addition, the equity score should be based on data readily available to facilities and calculated with a formula that can be understood readily by the general population.

Addressing Health Equity through Data Stratification

ASPN supports the evaluation of the stratification of the standardized readmission ratio (SRR), standardized transfusion ratio (STrR), standardized mortality ratio (SMR), and standardized hospitalization ratio (SHR) measures by dual eligibility status. The information gained by this stratification may inform clinical practices and care. The methodologies used for this data analysis should be available to providers with calculations readily replicable to promote transparency. ASPN additionally believes that it is appropriate to report measures by socio-demographic status (SDS) as appropriate. At a minimum, SDS factors for stratification should include dual eligibility status, age, race and ethnicity, insurance status, and geographic area of residence.

Patient COVID-19 Vaccination Measure

ASPN believes all medically-eligible health care professionals should be vaccinated against COVID-19 and supports ongoing efforts to provide COVID-19 vaccination at dialysis facilities. To the extent that CMS pursues a vaccination measure for ESRD patients, the denominator of this measure should only include patients eligible for vaccination under an existing emergency use authorization (EUA) or approval. As of August 31, COVID-19 vaccinations have only been authorized for children ages 12-17. For that reason,

³ Laster M, Soohoo M, Hall C, et al. Racial–ethnic disparities in mortality and kidney transplant outcomes among pediatric dialysis patients. *Pediatr Nephrol*. 2017;32(4):685-695. doi:10.1007/s00467-016-3530-2; Leonard MB, Donaldson LA, Ho M, Geary DF. A prospective cohort study of incident maintenance dialysis in children: An NAPRTC study. *Kidney Int*. 2003;63(2):744-755. doi:10.1046/j.1523-1755.2003.00788.x; Moxey-Mims M. Kidney Disease in African American Children: Biological and Nonbiological Disparities. *Am. J. Kidney Disease*, 2018;72(5):S17-S21. doi.org/10.1053/j.ajkd.2018.06.025.

⁴ Mehotra R, et al. Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States.

⁵ Fontanarosa PB, Bauchner H. Race, Ancestry, and Medical Research. *JAMA*. 2018;320(15):1539–1540. doi:10.1001/jama.2018.14438

⁶ Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. *JAMA*. 2019;322(2):113–114. doi:10.1001/jama.2019.5774

until children ages 11 and under are eligible for vaccination through an emergency use authorized vaccine, these patients should be excluded from any vaccination measure.

Thank you for the opportunity to provide these comments. Should you have any questions or wish to follow up, please contact Erika Miller, ASPN's Washington representative, at emiller@dc-crd.com.

Sincerely,

A handwritten signature in black ink that reads "Michael JG Somers, MD". The signature is written in a cursive, flowing style.

Michael JG Somers, MD
President